

REMARKS

This response to the final Office Action dated April 6, 2009 is respectfully submitted to be fully responsive to the § 103(a) rejection raised therein. Accordingly, favorable reconsideration on the merits and allowance are respectfully requested.

Claims 9-11 are pending in the present application.

Applicants thank the Examiner for withdrawing previous rejections as indicated in the Final Office Action.

I. Response to Rejection Under 35 U.S.C. § 103(a)

The rejection of claims 9-11 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,987,129 B2 (Mak) has been maintained.

Particularly, Examiner Kim concedes that Mak fails to illustrate the actual *treatment* of interstitial cystitis with a phosphodiesterase IV inhibitor such as roflumilast and ariflo. (*See* Office Action dated April 6, 2009, page 5, lines 3-4). The Examiner's rationale for maintaining the § 103 rejection is that it would have been obvious to one of ordinary skill in the art to employ phosphodiesterase IV inhibitors, such as roflumilast and ariflo, in a method for treatment of interstitial cystitis based on the teachings of Mak, which assertedly teaches that roflumilast and ariflo are equally as effective in the treatment of interstitial cystitis. Examiner Kim further asserts that there is a reasonable expectation of success to reach the claimed invention because Mak allegedly teaches and suggests the use of phosphodiesterase IV inhibitors, including roflumilast and ariflo, for the treatment of interstitial cystitis.

Applicants traverse and respectfully request reconsideration in view of the following remarks.

The present application is directed to agents for the treatment of chronic pelvic pain syndrome, comprising a phosphodiesterase 4 (PDE 4) inhibitor as an active ingredient. Chronic pelvic pain syndrome includes, *inter alia*, abacterial prostatitis, chronic pelvic pain syndrome and interstitial cystitis. The Examples in the present application show that the PDE 4 inhibitors inhibited infiltration of granulocytes in a rat antigen-induced cystitis model and that these inhibitors possess a therapeutic effect on the micturition reflex and bladder function in rat hydrochloric acid-induced cystitis model.

Mak teaches noninvasive methods for treating urogenital disorders using nitric oxide (NO) donors and other agents that either **interfere with the down-stream biochemical events leading to smooth muscle relaxation or block signals for smooth muscle contractions.**² Mak broadly lists various urogenital disorders, such as vaginismus, dyspareunia, and vulvodynia. Interstitial cystitis is listed among the group. Mak further lists a myriad of unrelated compounds (over 20) that are suitable for the method of treating urogenital that either interfere with the down-stream biochemical events leading to smooth muscle relaxation or block signals for smooth muscle contractions, including calcium channel blockers, potassium channel activators, estrogen-like compound and phosphodiesterase inhibitors.³

² See, Mak, U.S. 6,987,129 col. 9, ll. 46-50.

³ Id. at col. 9, l. 56 to col. 10, l. 16.

The difference between the present claimed method of treatment and the methods described in Mak is that Mak broadly teaches that **urogenital disorders** may be treated by various classes of compounds, such as NO donors, calcium channel blockers, HMG-CoA reductase inhibitors and phosphodiesterase 4 inhibitors. Mak fails to explicitly teach a method of treating chronic pelvic pain syndrome comprising administering an effective amount of a phosphodiesterase 4 inhibitor. In this regard, the Examiner asserts that Mack's teaching that PDE IV including the active agents such as roflumilast, ariflo also known as cilomilast are effective for the treatment of interstitial cystitis, is sufficient for one of ordinary skill in the art to employ roflumilast and cilomilast for the treatment of chronic pelvic pain syndrome (interstitial cystitis) with a reasonable expectation of success. Applicants respectively traverse.

Prior art cannot render a later invention unpatentable for obviousness unless the prior art enables any person skilled in the art, for which it pertains, to make and use the later invention.⁴ Examiner Kim concedes that Mak fails to disclose the actual treatment of interstitial cystitis with phosphodiesterase 4 inhibitors on page 8, lines 10-11 in the Office Action mailed October 2, 2008. (*See also*, Office Action dated April 6, 2009, page 5, lines 3-4). Example 9 in Mak discloses a method of mitigating symptoms associated with interstitial cystitis (IC). However, Mak discloses said process to **mitigate symptoms associated with interstitial cystitis** by using a vaginal ring containing lovastatin, a HMG-CoA reductase inhibitor, which supplies a continuous release of lovastatin.⁵ Mak does not *specifically* describe a method of treating interstitial cystitis with classes of agents known as phosphodiesterase 4 inhibitors and Mak does

⁴ *In re Kumar*, 418 F3d 1361, 76 USPQ2d 1048 (CAFC 2005).

⁵ U.S. 6,987,129 (Mak), Example 9 at col. 28, lines 15-26.

not teach that roflumilast and ariflo are equally as effective in treating interstitial cystitis. Therefore, Mak fails to describe how to use phosphodiesterase IV inhibitors to treat IC.

Furthermore, there would not be a reasonable expectation of success for the treatment of interstitial cystitis using phosphodiesterase 4 inhibitors based on the teachings of Mak. Mak generally lists phosphodiesterase 4 inhibitors, among others, are effective in treating a variety of **urogenital disorders**.⁶ In fact, Mak teaches that “[a]t this time there is no cure for IC, nor is there an effective treatment which works for everyone.”² Thus, a person of ordinary skill in the art would not be motivated to use phosphodiesterase 4 inhibitors to treat interstitial cystitis based on Mak. Accordingly, Mak does not enable one of ordinary skill in the art to use phosphodiesterase 4 inhibitors to treat chronic pelvic pain and therefore can render the presently claimed invention obvious. Withdrawal of the rejection of claims 9-11 is respectfully requested.

II. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

⁶ U.S. 6,987,129 (Mak), col. 2, lines 35-56; see also, col. 4, lines 46-57.

² U.S. 6,987,129 (Mak), col. 11, lines 53-54.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

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